BOX PATENT EXT.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. 047711/0100

In re: U.S. Patent No. 4,373,527

Patentee: Robert E. FISCHELL

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

THIRD YEAR REQUEST FOR *INTERIM* EXTENSION OF PATENT TERM
UNDER 35 U.S.C. § 156(d)(5)

Commissioner of Patents and Trademarks
Washington, D.C. 20231
BOX PATENT EXT.

Sir:

On January 28, 2000, The Johns Hopkins University ("Hopkins") timely filed an interim patent term extension application for the above U.S. Patent No. 4,373,527 ("the '527 patent"). The '527 patent was originally due to expire on Feb. 15, 2000, but with a one-year interim extension, it would expire on Feb. 15, 2001. On Feb. 7, 2000, the Patent Office sent a communication denying the one-year interim extension but permitting Hopkins an opportunity to request reconsideration. On March 27, 2000, following an interview between the undersigned and Ms. Karin Tyson of the Patent Office, Ms. Tyson sent a letter to the FDA stating that the '527 patent would be eligible for an extension "only if an application under section 515 of [the Act] was initially submitted prior to January 28, 2000 for the product Minimed 2007." Hopkins

followed up the interview with a formal Request for Reconsideration, which was filed on May 8, 2000. On May 8, 2001, the FDA responded to Ms. Tyson's March 27, 2000 letter, indicating that it was up to the Patent Office to determine whether the facts of this case satisfy the statute's requirement for an "initially" submitted application, but that MiniMed's PMA was currently under review by the FDA.

On July 11, 2001, Hopkins sent comments to the Patent Office responding to the FDA's May 8th letter, noting several important facts that clearly demonstrate the existence of an "initially" submitted application within the meaning of the statute. The FDA reviewed the initially submitted PMA and, as explained previously, the PMA was withdrawn after consultation with the FDA, but by no means abandoned. In the time between initial submission and initial withdrawal, there was review of the initially submitted PMA taking place, but that review did not end with the withdrawal of the PMA on March 20, 1992. Rather than abandoning the PMA, work between applicant and the FDA relating to the initially submitted PMA continued and intensified during the period leading up to the critical date as evidenced by the chronology of activities provided in the patentee's request for reconsideration, which is reproduced here for convenience:

Date	Description
10/26/99	fax to Pat Cricenti of FDA regarding MiniMed's intention to submit PMA application for the MIP system
11/19/99	fax to Mary Joe Robinson of FDA with proposed agenda for meeting to discuss MIP systems PMA application
12/7/99	meeting between MiniMed representatives and FDA regarding MIP system PMA application
12/23/99	letter to Pat Cricenti of FDA regarding results of 12/7/99 meeting to discuss MIP system

The record shows that the FDA and MiniMed were continuing to engage in activities and dialog related to the initially submitted PMA in preparation for its re-submission, which

represents a continuation of the review period described in (3)(B)(ii). All of these activities related to the initially submitted and withdrawn PMA, which was being prepared for re-submission during this period based on discussions with the FDA. As confirmed by the FDA's letter, the PMA was re-submitted on July 12, 2000, shortly after the critical date. The PTO's decision of ineligibility might have been correct if the PMA had been abandoned following its withdrawal, but that was not the case here. There is evidence in this record that the review period began with the initially submitted PMA and continued up to and past the critical date despite the "withdrawal" of the initially submitted PMA. The statute does not require a "pending" or "approvable" PMA, only an "initially" submitted PMA.

To date, however, the Patent Office has not responded to Hopkins' Request for Reconsideration and the clarifying remarks it submitted on July 11, 2001.

37 C.F.R. 1.790(a) specifies that a patentee must file a second or subsequent interim extension application during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. Because that deadline is again approaching and because Hopkins has yet to receive a final decision on its first-year interim extension, Hopkins herewith submits its third-year interim extension application and requests the PTO to grant a third-year interim extension for the '527 patent. The '527 patent is entitled to a third year interim extension because the FDA has not yet approved Minimed 2007 and there was an application under section 515 of [the Act] for the Minimed 2007 initially submitted prior to January 28, 2000, as explained in Hopkins' May 8, 2000 Request for Reconsideration.

The information required by 37 C.F.R. 1.790(c) is submitted in the following sections and in the attachments to this application.

STATEMENT THAT REGULATORY REVIEW PERIOD HAS NOT BEEN COMPLETED

As of the date of filing this application, the regulatory review period for Minimed 2007 has not been completed.

ITEMS REQUIRED BY 37 C.F.R. §§ 1.740 & 1.790 NOT SUBMITTED WITH FIRST INTERIM EXTENSION APPLICATION

The following information is submitted in accordance with 35 U.S.C. § 156(d) and 37 C.F.R. § 1.740, and follows the format and requirements set forth in 37 C.F.R. § 1.740.

"A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities" 37 C.F.R. § 1.740(a)(11).

Attached is a chronology that briefly describes the significant regulatory activities associated with Minimed 2007 since the last date on the list provided with the prior interim extension application (Exhibit 1).

"The prescribed fee for receiving and acting upon the application for extension," 37 C.F.R. § 1.740(a)(14).

Pursuant to 37 C.F.R. § 1.20(j)(3), a check in the amount of $ 220.00 is enclosed with this application.

"The name, address and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed," 37 C.F.R. § 1.740(a)(15).

Please direct all inquires and correspondence relating to this application for patent term extension to:

Stephen B. Maebius
Foley & Lardner
3000 K Street, N.W.
Wasington, DC 20007
202-672-5569

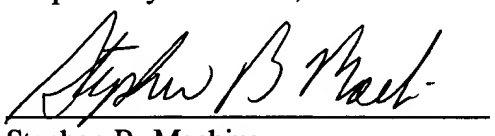
"A duplicate of the application papers, certified as such," 37 C.F.R. § 1.740(a)(16).

Enclosed is a certification that this application for patent extension, including its attachments, is being submitted as one original and one duplicate copy thereof (Exhibit 2).

"An oath or Declaration as set forth in 37 C.F.R. § 1.740(b)," 37 C.F.R. § 1.740(a)(ii).

The requisite declaration pursuant to 37 C.F.R. § 1.740(b) is attached as Exhibit 3.

Respectfully submitted,



January 14, 2002

Stephen B. Maebius
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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

EXHIBIT 1

Date	Significant Activity
1/29/01	submitted responses to questions contained in 11/20/00 FDA letter
2/5/01	submitted final PMA module to FDA
3/28/01	submitted information requested by FDA regarding purchasing controls
4/24/01	submitted amendment to PMA including minutes from prior meetings
5/24/01	notified by FDA that PMA review on hold because of NDA issues
9/24/01	submitted additional EMC testing information requested by FDA

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket No. 044711/0100

In re: U.S. Patent No. 4,373,527

Patentee: Robert E. Fischell

Assignee: The Johns Hopkins University

Issue Date: February 15, 1983

CERTIFICATION

Commissioner of Patents and Trademarks
Washington, D.C. 20231
BOX PATENT EXT.

Sir:

I, Stephen B. Maebius, do hereby certify that this accompanying application for an interim extension of the term of U.S. Patent No. 4,373,527 under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and one duplicate copy thereof.

Respectfully submitted,

Jan. 14, 2002
Date

Stephen B. Maebius
Registration No. 35,264

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Atty. Docket No. 047711/0100

In re: U.S. Patent No. 4,373,527

Patentee: Robert E. Fischell

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DECLARATION

Commissioner of Patents and Trademarks
Washington, D.C. 20231
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Sir:

As agent for the owner of record of U.S. Patent No. 4,373,527, I declare that:

(1) I am a patent attorney authorized to practice before the United States Patent and Trademark Office and I have general authority from the owner of United States Patent No. 4,373,527 to act on behalf of the owner in patent matters;

(2) I have reviewed and understand the contents of the accompanying application, which is submitted pursuant to 37 C.F.R. § 1.740 for an interim extension of U.S. Patent No. 4,373,527;

(3) I believe that U.S. Patent No. 4,373,527 is subject to an interim extension pursuant to 37 C.F.R. § 1.710;

(4) I believe an interim extension is justified under 35 U.S.C. § 156 and the applicable regulations; and

(5) I believe that U.S. Patent No. 4,373,527, for which this extension is sought, meets the conditions for interim extension of the term of a patent as set forth in 37 C.F.R. §§ 1.740 and 1.790.

BOX PATENT EXT.
U.S. Patent No. 4,373,527

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application and any extension of U.S. Patent No. 4,373,527.

Respectfully submitted,

Jan. 14, 2002
Date

Stephen B. Maebius
Registration No. 35,264

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